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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,057	04/22/1998	GARY F. GERARD	0942.4330002	5386

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EXAMINER	
NASHED, NASHAAT T	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/064,057	GERARD ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *26, 33, 117, 122-125, 137-147, and 149-161*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit: 1652

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejections made under 35 U. S. C. 112, first and second paragraphs.

After entering the after-final amendment filed May 3, 2004, claims 26, 33, 117, 122-125, 137-147, and 149-161 are pending and under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures for the reasons set forth in the prior Office actions, paper number 41 and that mailed January 2, 2004.

In response to the above objection to the specification, applicants argue that the examiner has not stated that the referred sequences are essential material.

Applicants' arguments filed 5/3/04 have been fully considered, but they are not deemed to be persuasive. The sequences required by the examiner are essential to understanding and interpreting the specification. Applicant is required to perfect their compliance with the sequence rules.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 26, 33, 117, 122-125, 137-147, and 149-161 are rejected under 35 U.S.C. 103 as being unpatentable over Soltis *et al.* in view of the state of the art at the time of the application was filed for the reasons set forth in the prior Office actions mailed January 2, 2004 and March 21, 2003.

In response to the above rejections, Applicants limited the claims to a recombinant method using eukaryotic host cell and argue that Soltis *et al.* do not teach the claimed invention as they teach the expression of the α- and β-subunits of AMV reverse transcriptase separately in *E. coli* and obtained a much lower specific activity. Also, applicants appear to be indignant regarding the comments made by the examiner on the specific activity in of 57,500 units/mg as the best the applicants can do.

Applicants' arguments filed 5/3/05 have been fully considered but they are not deemed to be persuasive. The examiner regrets any ill feeling to the applicants, which may have been caused by his remark about the specific activity, but applicants have provided Gerard *et al.* as evidence to support their claim of specific activity of >80,000 units per mg for the RNA-dependent DNA polymerase activity. The specification does not teach any preparation of AMV-reverse transcriptase with such an activity, and applicants have not provided any other evidence to indicate that such a preparation could be made. It appears that the applicants and examiner agrees that Soltis *et al.* do not teach the claimed invention. Contrary to applicants' assertion, one of ordinary skill in the art would have been motivated to carryout the claimed invention. He/She would have had the teaching of the prior art of record including Kawa *et al.* and Barr *et al.* (provided by the applicants) and the skills to express the α- and β-subunits of AMV transcriptase in eukaryotic host cell wherein both subunits are expressed in the same host cell as well as having the motivation and a reasonable expectation of obtaining the highest possible specific activity for the enzyme. Thus, the claimed invention stand rejected as being obvious over Soltis *et al.* and the state of the art. New claims 151-161 are included with these rejections because they are claiming the same subject matter.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652